UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,885	09/07/99	CURATOLO W	PC9824AJTJ

EXAMINER	
SHARAREH,S	
ART UNIT	**PAPER NUMBER**
1619	12

DATE MAILED: 09/13/01

HM12/0913

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/380,885	CURATOLO ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment filed on Jun 27, 2001 has been entered. Claims 1-53 are pending.

Response to Arguments

Any rejection that is not addressed in this Office Action is considered withdrawn in view of Applicant's arguments.

1. Claims 1-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over over Bechgaard et al EP 0080341, in view of the teachings of Drug Facts and Comparisons. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Applicant first argues that the references cited neither disclose nor motivate Applicant's invention. Specifically, Applicant asserts that GI side effects are not universally locally mediated such as those shown by anti-neoplastic drugs, and that such side effects may not necessarily be ameliorated by simply slowing down the rate of drug delivery and thus there is no motivation to delay the release of sertaline.

In response, Examiner states that first the recitation of instant claims are directed to oral dosage forms not IV infusion or IV bolus, intramuscular or subcutaneous formulation. Therefore, evaluating GI side effects of other drugs based on different routes of administration is not pertinent in this case. More importantly, nausea and vomiting is pathphysiologically distinct from gastritis and peptic ulcer or GI ulceration. As defined by Stedman's Medical Dictionary, Gastritis is inflammation of mucosal of the stomach. Thus, methods of minimizing gastritis induced by a drug is different from methods of managing drugs induced emesis, nausea, diarrhea. Therefore, comparisons

of the cause and management of such conditions are not commensurate with the scope of the claimed invention.

As previously indicated in Paper No. 5, and 9, Examiner takes the position that Sertraline is clearly documented to cause gastritis, and GI ulceration in up to 1% of the patients who utilize it (Facts). Further, it is conventional in the art to alleviate drug induced gastritis of an oral compound by formulating an enteric coated form of such compound. For example, it is well known in the art that Aspirin causes GI ulceration and gastritis, however, incidents of such adversed events are much reduced when an enteric coated form of asprin is utilized. In fact, Bechgaard discusses such conventional practice in the art in his Patent (see page 1-2).

Moreover, Bechgarrd clearly teaches release properties similar to the instant "immediate release" effects, described in page 3 of the instant specification. In Example 2-3, Bechgaard teaches that less than 10% of drug is released while drug is in the stomach. More specifically, Bechgaard indicates that his coating is erodable in an alkaline environment only, and the active substance is not released until the unit arrive at a section of the small intestine with an alkaline pH (see abstract, 2nd paragraph).

Further Bechgaard states that his compositions can be formulated so that the active drug is disintegrated in a predeteremined segment of the small intestine (see page 22, lines 20-22). In fact, Bechgard's Figure 2, depicts a near 70% release of the remainder of the active drug, 1.5 hours after it leaves the stomach. Accordingly, Bechgarrd teaches the pharamcokinetic properties of the instant claims.

Examiner restates his previous position that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Thus, one of ordinary skill in the art would have not needed to know the exact mechanism of Sertraline induced GI-upset, because as shown in the Drug Facts and Comparisons, Sertraline is associated with gastrointestinal side effects such as gastritis. Such side effect, as recognized in the art, is best alleviated by enteric coating of the compound to create a delayed release dosage form. Thus, preparing an enteric coated formulation of Sertaline flows naturally from the suggestions made in the art and therefore, there is motivation in the art to coat Sertraline.

Further, Bechgarrd suggests the use of anti-depressives as suitable active substance (page 8, line 24). Sertraline is an anti-depressive agent, therefore, there is suggestion in the art to formulate a delayed release formulation of Sertraline. Moreover, optimizing the concentration of coating material to facilitated disintegration at a desirable pH is well within skill level of an ordinary artisan. Therefore, one of ordinary skill in the art would have been motivated to modify Bechgarrd's formulation using Sertraline as the active drug.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, methods of preparing a enteric coated antidepressent formulation is well described by Bechgaard for drugs causing gastritis such as Indomethacin and Acetylsalicylic acid. Further, it is well within knowledge of an ordinary skill at the time the claimed invention was made that Sertraline shares the same type of gastric side effects as Indomethacin and Acetylsalicylic acid. Therefore, practicing similar concept as taught by Bechgarrd while using Sertraline as the active agent, is not hindsight reasoning, rather, *prima facia* obviousness. Accordingly, claims 1-53 stand rejected.

2. Claims 1-53 provisionally stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-105 of copending Application No. 09/380,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are directed to delayed release sertraline dosage forms and methods of use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that the double patenting reference is directed to a sertraline sustained release dosage form and that is a different invention than a delay and immedicate release.

In response, Examiner states that in determining whether a nonstatutory basis exists for a double patenting rejection, the following factual inquiries where considered:

(1) the scope and content of a patent claim and the prior art relative to a claim in the application at issue;

(2) the differences between the scope and content of the patent claim and the prior art as determined in (1) and the claim in the application at issue;

(3) the level of ordinary skill in the pertinent art; and

(4) any objective indicia of nonobviousness.

The conclusion of obvious - type double patenting is made in light of these factual determinations. See MPEP 804, B-1.

Furthermore, when considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure. The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619, 622 (CCPA 1970).

In the instant case, the claimed Sertraline formulation comprise (a) a core of comprising Sertraline and an osmagent and (b) an enteric coating. The double

patenting reference provides similar compositions having similar components. Accordingly, the scope of claimed composition and the provided teachings overlap. Further, as the composition of a sustain released formulation frequently utilizes a mixture of an osmagent and an active drug, one of ordinary skill in the art armed with the teachings of the double patenting reference would have been able to ascertain formulations not only with sustained release properties but also delayed release properties of Sertraline. Accordingly, in light of such overlapping teachings the provisional double patenting rejection is maintained.

Conclusion

3. No claims were allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from

8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 9/5/2001

DIANA DUDASH
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